

## Background Memo

<b>Document:</b>	Life Sciences Annex - Testing for food allergen proteins and gluten
<b>Date:</b>	October 2023
<b>Key changes:</b>	This is a document, scheduled for review that was developed with broad stakeholder engagement to describe the accreditation criteria applied to facilities undertaking testing for food allergen proteins and gluten.
<b>Background:</b>	
<p>This Annex has undergone a systematic review, resulting in the following revisions:</p> <ul style="list-style-type: none"> <li>• The document no longer references lateral flow technology (LFT), as accreditation for this technique has not been granted, and the specific accreditation criteria does not cover LFT accreditation.</li> <li>• Updated references to schedule 9 of the Australia New Zealand Food Standards Code (ANZFSC) have been incorporated.</li> <li>• Clarification has been provided regarding the requirement for validation when using a test kit beyond the manufacturer's validated scope.</li> <li>• It has been clarified that accreditation for swab analysis is exclusively offered for qualitative results.</li> <li>• The document now includes a reference to AOAC International Appendix N.</li> <li>• Clear guidance on reporting results above the LOQ to one decimal place has been added.</li> <li>• The requirement for a procedure to report results falling between the LOD and LOQ has been removed.</li> <li>• A reference to DIN EN 15633-1:2019-12 has been included.</li> </ul> <p>Please note that where changes are implemented after the review stage, these criteria will have a three-month implementation period. NATA expects that applicant and accredited facilities are likely already in compliance due to their alignment with industry practices determined through stakeholder consultation. Nonetheless, NATA strongly advises taking prompt action to ensure compliance during assessment activities where changes may be necessary.</p>	
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